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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,717	04/13/2000	Katsuya Daimon	472552000100	7198

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/548,717	Applicant(s) DAIMON ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9-22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-22 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' response to the office action filed on March 1, 2005 has been entered.

Status

2. Claims 1, 3-7, 9-22, 25 are pending. All arguments have been fully considered and thoroughly reviewed, and are deemed persuasive for the reasons that follow. This action is made FINAL necessitated by amendment.

New Grounds of Rejections necessitated by Amendment

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-7, 9-17, 19-20, 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Yamauchi et al. (USPN. 6,274,387).

With regard to the instant claim 1 and 25, Yamauchi et al. teach a method for isolating nucleic acids using nucleic acid-binding particulate carrier (silica-coated magnetic particles) which contains silica wherein Yamauchi et al. disclose that the method consists of

(a) mixing nucleic acid containing material with a nucleic acid- binding particulate carrier (silica coated magnetic particle) with a particle diameter of ranging from 1 to 200 um and more preferably ranging from 1 to 20 um, a pore diameter ranging from 1 to 100 nm, a pore volume of 0.1 to about 2.5ml/g (see column 4, lines 6-47, column 5, lines 48-67, column 6, lines

1-14, column 13, lines 10-19) and a nucleic acid extraction solution for allowing the nucleic acids to adsorb to the particulate carrier, to thereby bind the nucleic acids to the particulate carrier, the nucleic acids being bound to the silica particulate carrier via hydrogen bonds formed between hydroxyl groups on the particulate carrier surfaces and bases of the nucleic acids (see col. 8, line 52-56, col. 9, line 1-3 indicating hydroxyl group, col. 11, line 41-59);

(b) separating a composite of the nucleic acids and the particulate carrier from the mixture to remove contaminants (see col. 11, line 49-54, col. 13, lines 19-23);

(c) eluting and collecting the nucleic acids from the composite of the nucleic acids and the particulate carrier (see col. 11, line 54-59, col. 13, lines 23-30).

With reference to the instant claims 3-7, Yamauchi et al. also teach that the method comprises (i) the magnetic silica particulate carrier contains super paramagnetic metal oxide (see column 3, lines 49-60) and the metal oxide contained an amount of about 5 to about 50% by weight (see column 4, lines 62-64); (ii) a surface area of the particulate carrier ranges from 10 to 800 m² /g (see column 6, lines 15-22);

With regard to claims 9-17, Yamauchi et al. teach that (i) the nucleic acids comprises DNA, and/or RNA, and the nucleic acids containing biological material include body fluids (serum of HCV-infected persons) (see column 16, lines 15-18); (ii) the method contains extraction of nucleic acids with wash solutions containing chaotropic substance (guanidine thiocyanate) and alcohol (40% isopropanol) (see column 16, lines 19-55);

With regard to claims 19-20, Yamauchi et al. teach that the method further includes the detection of target nucleic acid comprising extracting the nucleic acids and amplifying the target

nucleic acid by polymerase chain reaction (PCR) (see column 13, lines 14-50, column 16, lines 19-60). Thus the disclosure of Yamauchi et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamauchi et al. (USPN. 6,274,387) and in view of Uematsu et al. (USPN. 5,945,525).

With regard to the instant claim 1 and 25, Yamauchi et al. teach a method for isolating nucleic acids using nucleic acid-binding particulate carrier (silica-coated magnetic particles) which contains silica wherein Yamauchi et al. disclose that the method consists of

(a) mixing nucleic acid containing material with a nucleic acid-binding particulate carrier (silica coated magnetic particle) with a particle diameter of ranging from 1 to 200 um and more preferably ranging from 1 to 20 um, a pore diameter ranging from 1 to 100 nm, a pore

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volume of 0.1 to about 2.5ml/g (see column 4, lines 6-47, column 5, lines 48-67, column 6, lines 1-14, column 13, lines 10-19) and a nucleic acid extraction solution for allowing the nucleic acids to adsorb to the particulate carrier, to thereby bind the nucleic acids to the particulate carrier, the nucleic acids being bound to the silica particulate carrier via hydrogen bonds formed between hydroxyl groups on the particulate carrier surfaces and bases of the nucleic acids (see col. 8, line 52-56, col. 9, line 1-3 indicating hydroxyl group, col. 11, line 41-59);

(b) separating a composite of the nucleic acids and the particulate carrier from the mixture to remove contaminants (see col. 11, line 49-54, col. 13, lines 19-23);

(c) eluting and collecting the nucleic acids from the composite of the nucleic acids and the particulate carrier (see col. 11, line 54-59, col. 13, lines 23-30).

However, Yamauchi et al. did not specifically teach washing solution containing ethanol concentration of 70% and 99% and detection of nucleic acid by using nucleic acid sequence based amplification (NASBA) and hybridization assay.

Uematsu et al. teach a method for extracting nucleic acids wherein Uematsu et al. disclose that the method comprises (i) first wash buffer containing guanidine thiocyanate and second wash buffer containing ethanol (70%) (see column 8, lines 24-46); (ii) the method further includes the detection of target nucleic acid comprising extracting the nucleic acids and amplifying the target nucleic acid by polymerase chain reaction (PCR) or nucleic acid sequence based amplification (NASBA) and detecting the target by nucleic acid hybridization assay (see column 8, lines 57-67 and column 9, lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of extracting nucleic acids as taught by Yamauchi et al. with

the method as taught by Uematsu et al. which is applicable to purification of nucleic acids because Uematsu et al. states that ‘for the purposes of purification of nucleic acids wash buffers include chaotropic material and ethanol’ (see column 7, lines 20-50). An ordinary practitioner would have been motivated to combine the method of Yamauchi et al. with the method of Uematsu et al in order to achieve reasonable expectation of success to develop a method to enhance quality of isolated of nucleic acids.

Response to arguments:

5. With regard to the rejection made in the previous office action under 35 USC 112, first paragraph (new matter), Applicants’ arguments and amendment are fully considered and found persuasive and the rejection is withdrawn in view of the amendment deleting the new matter.
6. With regard to the rejection made in the previous office action under 35 USC 112, second paragraph, Applicants’ arguments and the amendment are fully considered and found persuasive. The rejection is withdrawn in view of the amendment deleting the word “essentially”.
7. With regard to the rejection made in the previous office action under 35 USC 103(a), Applicants’ arguments and amendment are fully considered. The rejection is cancelled in view of the amendment and new grounds of rejections. The deletion of new matter, reinforced the same limitations present before the amendment, Further, the silica particulate carrier as recited in the instant claims do not exclude the surface containing polyacrylamide gel, because carrier itself is broader in scope and does not exclude the gel on its surface, more over the purpose of using the gel is to enhance the porosity and increase the adsorption on the silica particulate carrier and hence the instant claims are rejected based on prior art used in the earlier office action.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
Examiner, Art Unit 1637


JEFFREY FREDMAN
PRIMARY EXAMINER

5/6/05